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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/570,628

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Peter Hudson

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/570,628	Applicant(s) HUDSON ET AL.	
	Examiner Brenda L. Coleman	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/3/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-11 are pending in the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1 and 3-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a. Claims 1 and 3-11 are vague and indefinite in that it is not know what is meant by the variables R^1 , R^2 , R^3 and R^4 which are not defined within the claim.
- b. Claims 1 and 3-11 are vague and indefinite in that it is not know what is meant by the definitions of R1, R2, R3 and R4 where there are no variables within formula I.
- c. Claim 1 is vague and indefinite in that it does not end with a period indicating the end of the claim.
- d. Claim 6 is a substantial duplicate of claim 3 as the only difference is a statement of intended use, which is not given material weight. Note In re Tuominen 213 USPQ 89.
- e. Claim 7 is a substantial duplicate of claim 3 as the only difference is a statement of intended use, which is not given material weight. Note In re Tuominen 213 USPQ 89.

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- f. Claim 10 is a substantial duplicate of claim 3 as the only difference is a statement of intended use, which is not given material weight. Note In re Tuominen 213 USPQ 89.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1 and 3-11 are rejected under 35 U.S.C. 102(b) as being anticipated by HUDSON et al., WO 03/016316. Hudson teaches the compounds, compositions and method of use of the compounds of formula I where R³ is F as set forth in example 134.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being obvious over HUDSON et al., WO 03/016316.

The applied reference has a common inventor with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome

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by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2). The generic structure of Hudson embraces the compounds, compositions and method of use of the compounds of formula I as claimed herein. Example 134 on page 61, which anticipates the compounds, compositions and method of use of the compounds of the instant invention, differs only in the substituents R^1 , R^2 and R^3 as well as R^4 . Page 4, lines 6 and 7, defines the substituents R^1 , R^2 and R^3 as H, alkyl, O-alkyl, F, Cl or Br and R^4 as H, alkyl, optionally substituted phenyl, pyridyl, thienyl or furyl or is $-(CH_2)_e-R^8$ wherein e is 1, 2 or 3 and R^8 is H, alkyl, optionally substituted phenyl, pyridyl, thienyl or furyl, F, OH, O-alkyl, S-alkyl, O-acyl, NH_2 , NH-alkyl, $N(alkyl)_2$, NH-acyl, $N(alkyl)-acyl$, CO_2H , $CO_2-alkyl$, $CONH_2$, $CONH-alkyl$, $CON(alkyl)_2$, CN or CF_3 . The compounds, compositions and method of use of the compounds of formula I of the instant invention are generically embraced by Hudson in view of the interchangeability of the substitutions of the 1-methyl-4,10-dihydropyrazolo[5,4-b][1,5]benzodiazepine compounds. Thus, one of

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ordinary skill in the art at the time the invention was made would have been motivated to select for example chloro for instant R³ as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12, 21, 23, 26-33, 36-40, 49, 51 and 54-61 of copending Application No. 12/213,576. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula 1 of 12/213,576 embraces the compounds, compositions and method of use of the

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compounds of formula I of the instant invention where G^1 is formula 6; A^3 is $-\text{CH}=\text{CH}-$; A^4 , A^5 and A^{10} are all CH; A^6 is NH; A^7 and A^{11} are both C; A^8 is $\text{N}-\text{CH}_3$; A^9 is N; a is 1; b is 2; X^1 is NH; R^4 is $-(\text{CH}_2)_e\text{R}^8$ wherein e is 1 and R^8 is an optionally substituted phenyl; R^1 , R^2 and R^3 are each selected from H, alkyl, F and Cl.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 19, 21-24, 70, 73 and 74 of copending Application No. 11/659,798. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the compounds of formula 1b of 11/659,798 embraces the compounds, compositions and method of use of the compounds of formula I of the instant invention where G^1 is formula 6; A^3 is $-\text{CH}=\text{CH}-$; A^4 , A^5 and A^{10} are all CH; A^6 is NH; A^7 and A^{11} are both C; A^8 is $\text{N}-\text{CH}_3$; A^9 is N; a is 1; b is 2; X^1 is NH; R^4 is $-(\text{CH}_2)_e\text{R}^8$ wherein e is 1 and R^8 is an optionally substituted phenyl; R^1 , R^2 and R^3 are each selected from H, alkyl, F and Cl.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

6. Claims 1-11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 17, 21-27, 29-32, 35 and 36 of copending Application No. 10/486,715. Although the conflicting claims are not identical, they are not patentably distinct from each other because the

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compounds, compositions and method of use of the compounds of formula 1 of 10/486,715 embraces the compounds, compositions and method of use of the compounds of formula I of the instant invention where G^1 is formula 6; A^3 is $-\text{CH}=\text{CH}-$; A^4 , A^5 and A^{10} are all CH; A^6 is NH; A^7 and A^{11} are both C; A^8 is $\text{N}-\text{CH}_3$; A^9 is N; a is 1; b is 2; X^1 is NH; R^4 is $-(\text{CH}_2)_e\text{R}^8$ wherein e is 1 and R^8 is an optionally substituted phenyl; R^1 , R^2 and R^3 are each selected from H, alkyl, F and Cl.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624